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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/019,644 | 07/29/2002 | John C Kappes | 44276/242574 (5854-6) | 1101 |
| 826 | 7590 | 10/06/2003 | EXAMINER | |
| ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000 | | | LI, BAO Q | |
| | | ART UNIT | PAPER NUMBER | 10 |
| 1648 | | | | |

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/019,644 | KAPPES ET AL. | |
| | Examiner Bao Qun Li | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-32, drawn to a method for detecting a retrovirus genetic recombinant.

Group II, claim(s) 33-39, drawn to another method for detecting a retrovirus genetic recombinant, wherein the said genetic product is Tat.

Group III, claim(s) 40-51 and 59, drawn to a method for detecting a retroviral assay system for detecting a retroviral genetic recombinant having gag and pol functions.

Group IV, claim(s) 52-58, drawn to an indicator cell for indicating the presence of a retrovirus.

2. The inventions listed as Groups I to IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature of the current invention is directed to a method for detecting a retrovirus recombinant by using one or more helper function of retrovirus to permit the detection of said recombinant. However, this technical feature is already disclosed by the prior art as evidenced by Kafri et al. (J. Virol. 1999, Vol. 73, No. 1, pp. 576-584). Kafri et al. teach a method for producing a recombinant retrovirus vector by using three plasmids encoding different functions of a retrovirus and co-transfection of the three plasmids together in a cell line produce a recombinant lent virus vector pseudotyped with vesicular stomatitis virus G. the presence of such recombinant virus can be detected with a reporter gene expression as presented by gag gene product of p24.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

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The species I of retroviral coding sequence: 1). Gag, 2). Pro, 3). Pol. 4). Rt, 5). in, 6). Gag-pro, 7). Gag-pol.

The species II of detecting assay: a). FISH, b). PCR, c). antigen-detection, d). Tat transfer, e). Gag transfer and f). mobilization.

The species III of mutation: i). Silent mutation, ii). Stop codon, iii). Deletion and iv). Insertion.

The species IV of mobilized nucleic acid sequences: A). a marker gene, B). a retroviral nucleic acid, and C). said recombinant.

The species V of promoter: 1-a) a constitutive promoter and 1-b). inducible promoter.

The species VI, of lentivirus: 2-a). HIV, 2-b). SIV, 2-c). HIV-2, 2d). FIV, 2-e). EIV, 2-f). BIV, 2-g). CAEV and 2-h). OVINE.

Species VII of cell: 3-a). Hela cell, 3-b). 293T.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Claims 6 and 22 are corresponding to Species I. Claims 4, 20 and 51 are corresponding to species II. Claims 8 and 24 are corresponding to species III. Claims 10, 20, 26 and 52 are corresponding to species IV. Claim 31 is corresponding to the species V. Claim 43 is corresponding to species VI. The generic claims for species VII is claim 55.

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The following claim(s) are generic: The generic claims for species I is claims 6 and 22. The generic claims for species II are claims 4, 20 and 51. The generic claims for species III are claims 8 and 24. The generic claims for species IV are claims 10, 20, 26 and 52. The generic claim for species V is claim 31. The generic claims for species VI is claim 43 . Claim 55 is corresponding to species VII.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: different species have different structures and function that can not linked together under as ingle technical feature.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Bao Qun Li

October 01, 2003

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